contamination, do not touch tip of container to any surface. Replace cap after using.''

(2) *For ophthalmic drug products packaged in single-use containers.* ''To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.''

(3) *For ophthalmic drug products containing mercury compounds used as a preservative.* ''This product contains (name and quantity of mercury-containing ingredient) as a preservative. Do not use this product if you are sensitive to'' (select one of the following: ''mercury'' or ''(insert name of mercury-containing ingredient) or any other ingredient containing mercury).''

§ 349.55 Labeling of ophthalmic astringent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an ''astringent'' (select one of the following: ''eye'' or ''ophthalmic'') ''(insert dosage form, e.g., drops).''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' the following phrase: ''For the temporary relief of discomfort from minor eye irritations.''

(c) *Warnings.* In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading ''Warnings'' for products containing any ingredient identified in § 349.10:

(1) ''If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.''

(2) ''If solution changes color or becomes cloudy, do not use.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'': Instill 1 to 2 drops in the affected eye(s) up to four times daily.

§ 349.60 Labeling of ophthalmic demulcent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug(s), if any, and identifies the product as a ''lubricant'' or ''demulcent (lubricant)'' (select one of the following: ''eye'' or ''ophthalmic'') ''(insert dosage form, e.g., drops).''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' one or more of the following phrases:

(1) ''For the temporary relief of burning and irritation due to dryness of the eye.''

(2) ''For the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun.''

(3) ''For use as a protectant against further irritation or to relieve dryness of the eye.''

(4) ''For use as a lubricant to prevent further irritation or to relieve dryness of the eye.''

(c) *Warnings.* In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading ''Warnings'' for products containing any ingredient identified in § 349.12:

(1) ''If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.''

(2) ''If solution changes color or becomes cloudy, do not use.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'': Instill 1 or 2 drops in the affected eye(s) as needed.

§ 349.65 Labeling of ophthalmic emollient drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug(s), if any, and identifies the product as a ''lubricant'' or ''emollient (lubricant)'' (select one of the following: ''eye'' or ''ophthalmic'') ''(insert dosage form, e.g., ointment).''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' one or more of the following phrases:

(1) ''For the temporary relief of burning and irritation due to dryness of the eye.''

(2) ''For the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun.''

(3) ''For use as a protectant against further irritation or to relieve dryness of the eye.''

(4) ''For use as a lubricant to prevent further irritation or to relieve dryness of the eye.''

(c) *Warnings.* In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading ''Warnings'' for products containing any ingredient identified in § 349.14: ''If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'': Pull down the lower lid of the affected eye and apply a small amount (one-fourth inch) of ointment to the inside of the eyelid.

§ 349.70 Labeling of ophthalmic hypertonicity drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a ''hypertonicity'' (select one of the following: ''eye'' or ''ophthalmic'') ''(insert dosage form, e.g., drops).''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' the following phrase: ''For the temporary relief of corneal edema.''

(c) *Warnings.* In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading ''Warnings'' for products containing any ingredient identified in § 349.16:

(1) ''Do not use this product except under the advice and supervision of a doctor. If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a doctor.''

(2) ''This product may cause temporary burning and irritation on being instilled into the eye.''

(3) ''If solution changes color or becomes cloudy, do not use.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'': Instill 1 or 2 drops in the affected eye(s) every 3 or 4 hours, or as directed by a doctor.

§ 349.75 Labeling of ophthalmic vasoconstrictor drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug(s), if any, and identifies the product as a ''redness reliever'' or ''vasoconstrictor (redness reliever)'' (select one of the following: ''eye'' or ''ophthalmic'') ''(insert dosage form, e.g., drops).''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' the following phrase: ''Relieves redness of the eye due to minor eye irritations.''

(c) *Warnings.* In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading ''Warnings'' for products containing any ingredient identified in § 349.18:

(1) ''If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.''

(2) ''Ask a doctor before use if you have [in bold type] narrow angle glaucoma.''

(3) ''Overuse of this product may produce increased redness of the eye.''

(4) ''If solution changes color or becomes cloudy, do not use.''

(5) ''When using this product [in bold type] pupils may become enlarged temporarily.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'': Instill 1 to 2 drops in the affected eye(s) up to four times daily.

[53 FR 7090, Mar. 4, 1988, as amended at 65 FR 38428, June 21, 2000]

§ 349.78 Labeling of eyewash drug products.

(a) *Statement of identity.* The labeling of the product identifies the product with one or more of the following terms: ''eyewash,'' ''eye irrigation,'' or ''eye irrigating solution.''